PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	10/812,380
Filing Date:	March 29, 2004
Applicant:	Iftikhar Khan et al.
Group Art Unit:	3761
Examiner:	Leslie R. Deak
Title:	HYBRID ARTERIOVENOUS SHUNT
Attorney Docket:	1800-000001

DECLARATION UNDER 37 C.F.R. § 1.131

Sir:

I hereby declare under penalty of perjury as follows:

1. That I am a co-inventor of the above-identified application.

2. That the invention was conceived and reduced to practice in this country prior to March 15, 2004, the effective filing date of the United States Patent Application Publication No. 2005/0203457 to Smego, as evidenced by the e-mail and underlying draft patent application attached as Exhibit 1.

3. That the dates deleted or otherwise blacked out from Page 1 of Exhibit 1 are prior to March 15, 2004. (The e-mail addresses have been blacked out to maintain the inventor's privacy.)

4. That the e-mail and underlying draft patent application provide evidence that the invention was conceived and reduced to practice prior to March 15, 2004, the effective filing date of Smego.

5. That the invention has never been abandoned, suppressed, or concealed.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are being made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, and patent issuing thereon, or any patent to which this verified statement is directed.

Dated: 4/05/07

Iftikhar Khan, MD

Iftikhar Khan

Address: 747 W. WRIGHTWOOD UNIT C

CHICAGO IL 60614

EXHIBIT 1

37 C.F.R. § 1.131 Declaration of
Iftikhar Khan and Nazir Khan

U.S.S.N. 10/812,380

Jones, Stephanie

From: Iftikhar Khan [redacted]
Sent:
To: Jones, Stephanie
Subject: RE: Khan Hybrid Shunt

hi stefanie,

looks good. my dad had some minor corrections

thanks again

I khan

"Jones, Stephanie" <sjones@HDP.com> wrote:

> Hello Dr. Khan,
>
> This e-mail corresponds to a phone message I left for you.
>
> You can modify the application in whatever style is the most convenient for you. I know that you are quite computer savvy. If you prefer, you can use the track changes feature to make additions, comments, suggestions, deletions to the application.
>
> I will have the formalized drawings early next week. I will have them converted to PDF format and send the file to you.
>
> Thanks Again,
> Stephanie
>
> -----Original Message-----
> **From:** Jones, Stephanie
> **Sent:**
> **To:** 'Iftikhar Khan'; nazirKhan[redacted]
> **Cc:** Suter, David
> **Subject:** Khan Hybrid Shunt
>
> Good Afternoon Gentlemen,
>
> Here is a draft of the Khan Hybrid Shunt patent application. I would like your feedback on the claims and the specification to make sure that the application reflects the shunt and shunt implanting and use. Please note that some of the numbering in the Description section will change after the formal drawings are finalized.
>
> If you have any questions or comments please feel free to call or e-mail.
>
> Thanks Again,
> Stephanie

<< File: 1800-500001 patent application.doc >>
****

Stephanie D. Jones
Harness, Dickey and Pierce, P.L.C.
5445 Corporate Drive
Troy, MI 48038
(248)641-1274

****

Stephanie D. Jones
Harness, Dickey & Pierce, P.L.C.
(248) 641-1274 - Direct Dial
(248) 641-0270 - Fax

HYBRID ARTERIOVENOUS SHUNT

INTRODUCTION

[0001] The present invention relates to devices, systems and methods for subcutaneously positioning a graft and catheter for access to the vascular system of a patient.

BACKGROUND OF THE INVENTION

[0002] The present invention relates to methods and apparatus for subcutaneously positioning a graft and catheter for access to the vascular system of a patient. In particular, this invention relates to an arteriovenous (AV) shunt for use in conjunction with hemodialysis.

[0003] Hemodialysis is the purification of blood by removing toxic substances and restoring chemical balance using an extracorporeal dialysis machine. The process is used as a substitute for proper kidney function in those with renal failure. Despite the benefits, a persistent drawback of hemodialysis is patient morbidity and mortality caused by failure of and infection from the hemodialysis access site.

[0004] Hemodialysis access sites include arteriovenous grafts, arteriovenous fistulas and hemodialysis catheters. An arteriovenous graft is a tube surgically placed under the skin, which is connected to an arterial source on one end and a venous source on the other. The graft is accessed by the cannulas of the dialysis machine, so the blood is removed from the body, cleansed in the dialysis filter and then returned to the patient. An AV fistula is a

direct connection of an artery to a vein where a graft is not used. The vein is used for dialysis access. A hemodialysis catheter is a percutaneous tube placed through the skin and directly into the subclavian vein, internal jugular vein or femoral vein. The extracutaneous portion is used for dialysis access.

[0005] Each of these access methods is problematic because they require anastomosis to a vein which causes vein damage. Furthermore, the weak veins of renal failure patients may not accommodate certain access methods.

[0006] In AV grafts, neointimal hyperplasia is caused when the cells of the inner layer of the vein hypertrophy and multiply in response to the high blood flow and pressure of the arteries. This multiplication along with turbulent flow causes frequent venous outflow obstruction and resultant clotting and failure of the AV graft. (Paulson, W.D.; Ram, S.J.; Zibari, G.B., "Vascular Access: Anatomy, Examination, Management", *Semin. Nephrol.*, Vol. 22, No. 3, May 2002, pp. 183-194). In AV fistulas, the common cause of failure is formation of venous aneurysms and clotting on the venous portion of the graft. Venous aneurysms are caused because of the flow pressure differential between the high pressure grafted artery and the vein. High pressure arterial flow through the thin walls of the veins cause damage because veins lack the prominent arterial layers of elastic and muscular tissue. These aneurysms then form clots because of the turbulent, irregular blood flow and subsequently the AV fistula completely clots off and fails. [U.S. Patent Nos. 6,102,884; 6,086,553; 5,556,426; 4,822,341; 4,654,033; 4,479,798; 3,998,222; 3,826,257; 3,818,257; 3,818,511 - hereby

incorporated by reference.] Hemodialysis catheters are the least preferred in the surgical community. The large bore catheters can last from two months to one year and are frequently complicated by infection and clotting because the limbs of the catheters are outside of the skin.

[0007] It would be desirable to have an arteriovenous device placed subcutaneously that does not require anastomisis to a vein and utilizes a single lumen venous outflow catheter. It would also be desirable to have an arteriovenous device that provides long term patency, prevents clotting and minimizes infection.

SUMMARY

[0008] The present invention provides an arteriovenous shunt comprising:

a. an arterial graft comprising a body, a lead end and a terminal end, wherein said lead end is operable for subcutaneous connection to an artery by anastomosis;

b. a single lumen venous outflow catheter comprising an intake end and depositing end, wherein said depositing end is operable for insertion through a vein into the right atrium of the heart; and

c. a cuff comprising an inlet and an outlet, wherein:

i. said inlet is connected to said terminal end of said subcutaneous graft; and

ii. said outlet is connected to said intake end of said venous outflow catheter.

[0009] The present invention also provides a system for performing hemodialysis on a patient comprising:

a. an arteriovenous shunt comprising:

i. an arterial graft comprising a body, a lead end and a terminal end, wherein said lead end is operable for subcutaneous connection to an artery by anastomosis; and

ii. a single lumen venous outflow catheter comprising an intake end and a depositing end, wherein said depositing end is operable for insertion through a vein into the right atrium of the heart; and

iii. a cuff comprising an inlet and an outlet, wherein:

1. said inlet is connected to said terminal end of said subcutaneous graft; and

2. said outlet is connected to said intake end of said venous outflow catheter; and

b. a hemodialysis apparatus.

[0010] The present invention additionally provides a method of performing hemodialysis on a patient comprising:

a. inserting an arteriovenous shunt into a patient, wherein said arteriovenous shunt comprises:

i. an arterial graft comprising a body, a lead end and a terminal end, wherein said lead end is operable for subcutaneous connection to an artery by anastomosis;

ii. a single lumen venous outflow catheter comprising an intake end and depositing end, wherein said depositing end is operable for insertion through a vein into the right atrium of the heart; and

iii. a cuff comprising an inlet and an outlet, wherein:

1. said inlet is connected to said terminal end of said subcutaneous graft; and

2. said outlet is connected to said intake end of said venous outflow catheter;

b. connecting said arterial graft to a hemodialysis apparatus;

c. collecting blood from the patient through said subcutaneous graft;

d. passing said blood through the hemodialysis apparatus;

e. collecting purified blood from hemodialysis apparatus; and

f. transmitting said purified blood through said cuff into said venous outflow catheter.

[0011] It has been found that the methods and apparatus of this invention afford benefits over methods and apparatus among those known in the art. Such benefits include one or more of long term patency, prevention of clotting and minimizing infection. Further benefits and embodiments of the present invention are apparent from the description set forth herein.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] The present invention will become more fully understood from the detailed description and the accompanying drawings, wherein:

[0013] Figure 1 depicts an arteriovenous shunt of the present invention in an upper extremity.

[0014] Figure 2 depicts an arteriovenous shunt of the present in a lower extremity.

[0015] **[Figure Suggestions]**

[0016] It should be noted that the figures set forth herein are intended to exemplify the general characteristics of an apparatus, materials and methods among those of this invention, for the purpose of the description of such embodiments herein. These figures may not precisely reflect the characteristics of any given embodiment, and are not necessarily intended to define or limit specific embodiments within the scope of this invention.

DESCRIPTION

[0017] The present invention provides devices, systems and methods for subcutaneously positioning a graft and catheter for access to the vascular system of a patent.

[0018] The following definitions and non-limiting guidelines must be considered in reviewing the description of this invention set forth herein.

[0019] The headings (such as "Introduction" and "Summary,") and sub-headings (such as "Surgical Methods") used herein are intended only for general

organization of topics within the disclosure of the invention, and are not intended to limit the disclosure of the invention or any aspect thereof. In particular, subject matter disclosed in the "Introduction" may include aspects of technology within the scope of the invention, and may not constitute a recitation of prior art. Subject matter disclosed in the "Summary" is not an exhaustive or complete disclosure of the entire scope of the invention or any embodiments thereof.

[0020] The citation of references herein does not constitute an admission that those references are prior art or have any relevance to the patentability of the invention disclosed herein. Any discussion of the content of references cited in the Introduction is intended merely to provide a general summary of assertions made by the authors of the references, and does not constitute an admission as to the accuracy of the content of such references. All references cited in the Description section of this specification are hereby incorporated by reference in their entirety.

[0021] The description and specific examples, while indicating the embodiment of the invention, are intended for purposes of illustration only and are not intended to limit the scope of the invention. Moreover, recitation of multiple embodiments having stated features is not intended to exclude other embodiments having additional features, or other embodiments incorporating different combinations stated of the features.

[0022] As used herein, the words "preferred" and "preferably" refer to embodiments of the invention that afford certain benefits, under certain circumstances. However, other embodiments may also be preferred, under the

same or other circumstances. Furthermore, the recitation of one or more preferred embodiments does not imply that other embodiments are not useful, and is not intended to exclude other embodiments from the scope of the invention.

[0023] As used herein, the word 'include" and its variants is intended to be non-limiting, such that recitation of items in a list is not to the exclusion of other like items that may also be useful in the materials, compositions, devices, and methods of this invention.

Materials

[0024] An embodiment of this invention consists of 3 parts. The first part is a flexible graft. In a preferred embodiment, the flexible material is polytetrafluoroethylene (PTFE). The graft measures from about 1 to 8 mm (but can be larger or smaller depending on the patient) in diameter and from about 1 to 15 cm in length. All lengths and diameters can vary depending on the size of the patient, the vein or artery used and the extremity length of the patient. This graft is placed under the skin-via strict sterile surgical technique and connected to the artery (brachial, axillary, subclavian or femoral) via careful anastomosis. This graft can be used for dialysis and can be accessed by using dialysis cannulas in a sterile fashion.

[0025] The second part consists of a single lumen venous outflow catheter. The venous outflow catheter has a smaller diameter than the PTFE

graft. In a most preferred embodiment, the catheter is 1 mm smaller in diameter than the graft.

[0026] Venous outflow catheters have a diameter from about 1.5 mm to about 2.0 mm. In a most preferred embodiment of this invention, the catheter diameter is 5 mm. As previously mentioned, the catheter size will vary depending on the age and/or body mass of the patient.

[0027] The single lumen venous outflow catheter is connected to the PTFE graft by surgical anastomosis over a Teflon cuff. This catheter will be constructed from polyurethane or silicone, other suitable materials can be used.

[0028] There is no anstamosis to a vein in embodiments of this invention thus eliminating the frequent problems that exist when a high flow system transmits into a vein such as venous aneurysms in AV fistulas, and neointimal hyperplasia in AV grafts.

Methods of Use

[Dr. Khan - Numbering will be modified based on new figures]

Surgical Methods

[0029] Figure 1 demonstrates embodiments of an arteriovenous shunt functioning in the upper extremity, anastanastomosed to the brachial or axillary artery. Blood will flow from the high pressure brachial or axillary artery [I] into the flexible graft [II] . The graft can be accessed in the usual sterile fashion, by the dialysis cannula [III] closest to the artery. The blood will then be filtered through the dialysis machine [IV], the toxins removed, and then returned back into the flexible graft via the other dialysis cannula closest to the Teflon cuff [V]. The

purified blood then flows via the venous outflow catheter [VI] directly into the right atrium [VII]. At other times a high flow system is maintained directly to the right atrium

[0030] Figure 2 demonstrates the shunt functioning in the lower extremity, anastanastomosed to the femoral artery. Blood will flow from the high pressure femoral artery [I] into the flexible graft [II]. The graft can be accessed in the usual sterile fashion, by the dialysis cannula [III] closest to the artery. The blood will then be filtered through the dialysis machine [IV], the toxins removed, and then returned back into the PTFE graft via the other dialysis cannula closest to the Teflon cuff [V]. The purified blood then flows via the venous outflow catheter [VI] directly into the right atrium [VII].

[0031] The venous outflow catheter measures from about 1 to 8 mm in diameter and from about 2 to 30 cm in length. All lengths and diameters can vary depending on the size of the patient, the vein or artery used and the extremity length of the patient.

[0032] These single lumen catheters can be advanced in the upper extremity through a vein into the right atrium. In a preferred embodiment, the axillary, subclavian or jugular vein is used. In the lower extremity, they will be advanced through a vein, preferably the external iliac vein, into the inferior vena cava and then the right atrium.

[0033] As shown in Figures 1 and 2, blood will flow from the high pressure artery into the PTFE graft. The graft can be accessed in the usual sterile fashion, by the dialysis cannula closest to the artery. The blood will then

be filtered through the dialysis machine, the toxins removed, and then returned back into the PTFE graft via the other dialysis cannula closest to the Teflon cuff. The purified blood then flows via the venous outflow catheter directly into the right atrium. The high flow system controlled by the hemodialysis apparatus is maintained directly to the right atrium.

[0034] The surgical technique for these procedures is best suited for a vascular surgical text or journal. (Benedetii, E.; DelPino, A; Cintron J., Duarle, B., "A New Method of Creating an Arteriovenous Graft Access", *Am. J. Surg.*, Vol. 171, No. 3, Mar. 1996, pp. 369-370.) It is understood that one skilled in the art would recognize modifications needed to surgical procedures depending on the dimensions of the graft and individual patient needs.

Methods of Performing Hemodialysis

[0035] Embodiments of this invention include methods of performing hemodialysis on a patient. First, the arteriovenous shunt is inserted into the patient subcutaneously using open surgical methods. The PTFE graft is anastomosed to an artery and a Teflon cuff is attached to the terminal end of the graft. The intake end of the venous outflow catheter is attached to the Teflon cuff. A vein is "cut down" and a glide wire is used to pass the catheter through the vein and into the right atrium. A pull string stitch is then used to close the vein around the catheter and prevent bleeding from the "cut down". Blood is removed from the patient through the subcutaneous graft and is passed through the hemodialysis apparatus for purification. Purified blood is collected from the

hemodialysis apparatus and then transferred through the cuff into the venous outflow catheter. The purified blood is then transferred through the catheter into the patient's right atrium through the inferior vena cava.

CLAIMS

What is claimed is:

1. An arteriovenous shunt comprising:

a. an arterial graft comprising a body, a lead end and a terminal end, wherein said lead end is operable for subcutaneous connection to an artery by anastomosis; and

b. a single lumen venous outflow catheter comprising an intake end and depositing end, wherein said depositing end is operable for insertion through a vein into the right atrium of the heart; and

c. a cuff comprising an inlet and an outlet, wherein:

i. said inlet is connected to said terminal end of said subcutaneous graft; and

ii. said outlet is connected to said intake end of said venous outflow catheter.

2. The arteriovenous shunt of claim 1 wherein said subcutaneous graft is made of polytetrafluoroethylene (PTFE).

3. The arteriovenous shunt of claim 1, wherein said arterial graft has a diameter from about 1 mm to about 8 mm and a length from about 1 cm to about 15 cm.

4. The arteriovenous shunt of claim 3, wherein said arterial graft has a diameter of from about 6 mm to about 8 mm and a length from about 5 cm to about 10 cm.

5. The arteriovenous shunt of claim 1, wherein said artery is the brachial, axillary, subclavian or femoral artery.

6. The arteriovenous shunt of claim 1, wherein said cuff is Teflon.

7. The arteriovenous shunt of claim 1, wherein said venous outflow catheter has a diameter from about 1 mm to about 8 mm and a length of from about 2 cm to about 30 cm.

8. The arteriovenous shunt of claim 1, wherein said venous outflow catheter has a diameter from about 5 mm to about 7 mm and a length of from about 19 cm to about 30 cm.

9. The arteriovenous shunt of claim 1, wherein said venous outflow catheter is made of polyurethane or silicone.

10. The arteriovenous shunt of claim 1, wherein said vein is the axillary, subclavian, jugular, femoral or external iliac vein.

11. The arteriovenous shunt of claim 1, wherein said venous outflow catheter has a diameter of about 1 mm smaller than the subcutaneous graft.

12. A system for performing hemodialysis on a patient comprising:

a. an arteriovenous shunt comprising:

i. an arterial graft comprising a body, a lead end and a terminal end, wherein said lead end is operable for subcutaneous connection to an artery by anastomosis; and

ii. a single lumen venous outflow catheter comprising an intake end and depositing end, wherein said depositing end is operable for insertion through a vein into the right atrium of the heart; and

ii. a cuff comprising an inlet and an outlet, wherein:

1. said inlet is connected to said terminal end of said subcutaneous graft; and

2. said outlet is connected to said intake end of said venous outflow catheter; and

b. a hemodialysis apparatus.

13. The system according to claim 12, wherein said venous outflow catheter has a diameter of about 1 mm smaller than said subcutaneous graft.

14. The system according to claim 12, wherein said artery is the brachial, axillary, subclavian or femoral artery.

15. The system according to claim 12, wherein said vein is the axillary, subclavian, jugular, femoral or external iliac vein.

16. A method of performing hemodialysis on a patient comprising:

a. inserting an arteriovenous shunt into a patient, wherein said arteriovenous shunt comprises:
    i. an arterial graft comprising a body, a lead end and a terminal end, wherein said lead end is operable for subcutaneous connection to an artery by anastomosis; and
    ii. a single lumen venous outflow catheter comprising an intake end and depositing end, wherein said depositing end is operable for insertion through a vein into the right atrium of the heart; and
    iii. a cuff comprising an inlet and an outlet, wherein:
        1. said inlet is connected to said terminal end of said subcutaneous graft; and
        2. said outlet is connected to said intake end of said venous outflow catheter;
b. connecting said arterial graft to a hemodialysis apparatus;
c. collecting blood from the patient through said subcutaneous graft;
d. passing said blood through the hemodialysis apparatus;
e. collecting purified blood from hemodialysis apparatus; and
f. transmitting said purified blood through said cuff into said venous outflow catheter.

17. The method according to claim 16 wherein said venous outflow catheter has a diameter of about 1 mm smaller than said subcutaneous graft.

18. The method according to claim 16, wherein said artery is the brachial, axillary, subclavian or femoral artery.

19. The method according to claim 16, wherein said vein is the axillary, subclavian, jugular, femoral or external iliac vein.

ABSTRACT OF THE DISCLOSURE

An apparatus for positioning a graft and catheter operable for subcutaneous access to the vascular system of a patient. A surgically created, hybrid arteriovenous shunt is provided which comprises a flexible graft and a venous outflow catheter connected to the graft via surgical anastomosis over a Teflon cuff. The graft is connected to an arterial source and then to a single lumen venous outflow catheter which deposits dialyzed blood directly into the heart at the right atrium. Methods of surgical placement and performing hemodialysis using embodiments of the apparatus are provided.